UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,968	07/26/2006	James L. Meisel	60045(50177)	5803

21874 7590 11/10/2010

EDWARDS ANGELL PALMER & DODGE LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER	
PORTER, RACHEL L	
ART UNIT	**PAPER NUMBER**
3626	

MAIL DATE	DELIVERY MODE
11/10/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,968	MEISEL ET AL.	
	Examiner	Art Unit	
	RACHEL L. PORTER	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,24 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-16,24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This communication is in response to the preliminary amendment in the application, filed 8/13/10. Claims 1-16 and 24-25 are pending. Claims 17-23 have been cancelled.

Claim Rejections - 35 USC § 101

2. The rejection of Claim, under 35 U.S.C. 101, is hereby withdrawn due to the amendment filed 8/13/10.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 has been amended to include the following steps: "a) conducting a visit with an outpatient; b) ordering a test at a laboratory based on the visit; c) subsequent to

steps a) and b), receiving first data relating to the test from a laboratory via electronic data interchange to the server…"

In particular, the Applicant does not point to, nor was the Examiner able to find, any support for this newly added claim language within the specification as originally filed. The specification does not disclose conducting a visit with an outpatient and then ordering a test at a laboratory based on the visit. Therefore, the specification further does not disclose the recited time specificity (i.e. c) subsequent to steps a) and b)) of receiving first data relating to the test from a laboratory via electronic data interchange to the server…"

Claims 2-8 inherit the deficiencies of claim 1 through dependency and are therefore also rejected.

The analysis of claim 1 may also be applied to claim 9, which has been amended to include similar limitations (performing the steps of: a) conducting a visit with an outpatient; b) ordering a test at a laboratory based on the visit; c) subsequent to steps a) and b), receiving first data relating to the test from a laboratory via electronic data interchange to the server…")

Claim 10 has been amended to recite "concluding a visit between the clinician and the outpatient." The Applicant does not point to, nor was the Examiner able to find, any support for this newly added claim language within the specification as originally filed. In particular, the specification does not disclose conducting a visit with an

outpatient, and therefore does not disclose "concluding a visit between the clinician and the outpatient."

Claims 11-16 inherit the deficiencies of claim 10 through dependency, and are therefore also rejected.

As such, the Applicant is respectfully requested to clarify the aforementioned issues and to specifically point out support for the newly added limitations in the originally filed specification and claims, or to cancel the new matter in the reply to this Office Action.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 has been amended to recite "*automatically electronically* sending said patient communication including said prescription to said patient." It is unclear to the Examiner if the Applicant intends to claim that the actual patient receives an "electronic prescription" (i.e. sent **to** the patient) or if an electronic prescription is transmitted/sent to a pharmacy ***for*** a patient.

Furthermore, regarding electronic transmission directly to the patient, it is not clear what media are used for the patient to receive, or carry said prescription to a designated pharmacy. (Patient computer, magnetic card, smartcard) A review of the

applicant's specification (par. 37,41) suggests transmitting a prescription via a link to a pharmacy. (*The medical communication system 210 includes provides written, faxed or e-mailed prescriptions directly to pharmacies 219, which are initiated by a clinician when interacting with a medplate described below.*—par. 41)

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-3 and 9-12, and 14-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Myers et al. (US 7464021 B1)

[claim 1] Myers discloses the method of providing medical communications from a clinician to patients in an outpatient environment having a server, (col. 2, lines 35-60) comprising the steps of:

- conducting a visit with an outpatient; (col. 7, lines 38-44; 65-col. 8, line 10)
- ordering a test at a laboratory based on the visit; (col. 7, lines 38-44; 65-col. 8, line 10)

- subsequent to conducting the visit and ordering the test at a lab, receiving first data relating to the test from a laboratory via electronic data interchange to the server; (col. 5, lines 35-59; col. 8, lines 3-10)
- retrieving from the server second data relating to a patient associated with the first test data; (col. 5, lines 52-67-e.g. patient name, list data)
- selecting a medplate based upon the first test data; (col. 6, lines 21-42)
- auto populating the medplate from the server based upon the first test data and the second patient data; (col. 6, lines 21-42)
- applying at least one rule to select default textual fragments based upon the first test data; (col. 6, lines 21-35-- *tests capable of interpretation by the system independently of a clinician, each template is associated with one or more specific test result values or a range of test result values for each particular test type).*
- providing from the server alternative textual fragments within the medplate; (col. 6, lines 6, lines 35-42-- *If one or more placeholders are present in the selected template, at step 220, additional data is embedded into the text of the template. The data may be numerical or textual result for the test….)*
- presenting the medplate from the server for review by the clinician; (col. 7, lines 29-36)
- receiving selection input regarding use of the default and alternative textual fragments to modify the medplate from the clinician; (col. 8, lines 65-col. 9, line 5)

- automatically generating in the server a correspondence based upon the modified medplate; and (col. 8, lines 45-55; col. 9, lines 5-26)
- automatically providing the correspondence to the patient from the server, wherein the server provides the correspondence via a means selected from electronic mail and generating a traditional postal letter. (col. 7, lines 54-64)

[claims 2, 3] Myers discloses method, wherein the at least one rule is an inclusionary rule and wherein the at least one rule is an exclusionary rule. (col. 8, lines 22-40; col. 9, lines 15-26—information provided based on thresholds/cut-offs)

[claim 9] Myers discloses a non-transitory computer-readable medium whose contents cause a computer system to perform a method for generating physician to patient communication in an outpatient environment having a server (col. 3, lines 34-col. 4, line 35) , the computer system having a server program and a client program (Figure 3) with functions for invocation by performing the steps of:.

- conducting a visit with an outpatient; (col. 7, lines 38-44; 65-col. 8, line 10)
- ordering a test at a laboratory based on the visit; (col. 7, lines 38-44; 65-col. 8, line 10)
- subsequent to conducting a visit with an outpatient and ordering the test at a laboratory, receiving first data relating to a the test from a laboratory via electronic data interchange to the server; (col. 5, lines 35-59; col. 8, lines 3-10)

- retrieving from the server second data relating to a patient associated with the first test data; (col. 5, lines 52-67-e.g. patient name, list data)
- selecting a medplate based upon the first test data; (col. 6, lines 21-42)
- auto populating the medplate from the server based upon the first test data and the second patient data; (col. 6, lines 21-42)
- applying at least one rule to select default textual fragments based upon the first test data; col. 6, lines 21-35-- *tests capable of interpretation by the system independently of a clinician, each template is associated with one or more specific test result values or a range of test result values for each particular test type).*
- providing from the server alternative textual fragments within the medplate; (col. 6, lines 6, lines 35-42-- *If one or more placeholders are present in the selected template, at step 220, additional data is embedded into the text of the template. The data may be numerical or textual result for the test….)*
- presenting the medplate from the server for review by the physician; (col. 7, lines 29-36)
- receiving selection input regarding use of the default and alternative textual fragments to modify the medplate from the physician; (col. 8, lines 65-col. 9, line 5)
- automatically generating in the server a correspondence based upon the modified medplate; (col. 8, lines 45-55; col. 9, lines 5-26)
- automatically electronically providing the correspondence to the patient from the server. (col. 8, lines 45-55; col. 9, lines 5-26)

[claim 10] Myers discloses a method for generating follow up patient communication from a clinician to an outpatient using a computer for facilitating interaction between the clinician and the computer comprising:

- concluding a visit between the clinician and the outpatient; (col. 7, lines 38-44; 65-col. 8, line 10)
- providing a repository of snippets including patient text and providing a database in the computer; (col. 6, lines 21-42)
- displaying information to the clinician from said database regarding a selected the outpatient using a said display device of the computer; (col. 6, lines 43-51—e.g. listing templates and results info.)
- receiving from the clinician via an interface of the computer a selection of at least one snippet from said repository of snippets; (col. 6, lines 42-65)
- displaying to the clinician at least a portion of said selected snippet using said display; (col. 6, lines 50-65)
- enabling interaction by the clinician with said snippet using said interface to select at least a portion of said snippet; and (col. 6, lines 55-col. 7, line 14)
- automatically generating patient communication based upon the interaction with said snippet, and (col. 8, lines 45-55; col. 9, lines 5-26)

- automatically electronically sending the outpatient communication to the selected patient from the computer subsequent to the visit. (col. 8, lines 45-55; col. 9, lines 5-26)

[claim 11] Myers discloses the method of claim 10, wherein said interaction with said snippet includes selecting items from a menu. (col. 6, lines 45-51—list reads on "menu")

[claim 12] Myers discloses the method of claim 10, wherein said interaction with said snippet includes selecting or deselecting a text portion. (col. 6, lines 45-55; col. 8, lines 36-54-selection of the template and addition of placeholder information entails the selection/deselection of data.)

[claim 14] Myers discloses the method of claim 10, wherein said interaction with said snippet includes inserting one or multiple words at a predefined location. (col. 6, lines 50-60; col. 8, lines 45-55- tagged placeholders)

[claim 15] Myers discloses the method of claim 10, wherein said interaction with said snippet includes importing data from said database. (col. 5, lines 42-47; col. 6, lines 20-65-- *the test results may either be input into the memory of the remote computer by a clinician or personnel associated with the clinician, or received directly from the output of a medical testing device. At step 200, the test results are received from one of the remote computers 28, preferably via the network and central server.*)

[claim 16) Myers discloses the method of claim 15, wherein said importing data from said medical database includes displaying one or more of the following: EKG traces, an X-ray image, a CT image and a tangible manifestation of a test result. (col. 50, lines 34-60- *The results may be in various forms, including numerical values, textual observations, images of X-rays, scans and/or photographs, or any of a number of recognized forms and formats of medical test results;* col. 7, lines 48-65--*Once the results distribution method is determined by the system, the results are distributed to the patient at step 246*)

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers in view of Official Notice.

[claim 4, 13] Myers discloses a method of providing correspondence to an outpatient from a clinician by selecting or deselecting text (e.g. templates), but does not expressly disclose using check boxes, blank fill in boxes and boxes with pull-down menu/ pull-down menus.

However, the use of check boxes, blank fill in boxes and boxes with pull-down menu/ pull-down menus to select or input data is old and well-known in the art. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Myers to include the use of check boxes, blank fill in boxes and boxes with pull-down menu/ pull-down menus to select or input data. One would have been motivated to include this feature to facilitate the entry of information, thereby providing a more effective system and method for responding to inquiries from patients regarding medical care test results (Myers: col. 2, lines 20-31)

11. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Myers in view of Joao (US 20010032099 A1)

[claim 5] Myers discloses a method, further comprising the steps of storing a calendar date for an action, based upon the correspondence, (Col. 10, lines 41-45), but does not expressly disclose automatically generating a reminder related to the action on the calendar date.

Joao discloses a healthcare method/system storing date information relating to medical treatments/procedures (appointments) (par. 268; Figure 11 A) and automatically generating reminders relating to the action on the calendar date. (par. 269) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Myers with the teaching of Joao to store date information relating to a correspondence and generate reminders regarding follow-

up medical appointments (i.e. automatically generating a reminder related to the action on the calendar date.) As suggested by Joao, one would have been motivated to include this feature to ensure that a proper treatment and/or procedure is performed on the patient, and/or to ensure that a subsequent treatment and/or treatments are performed as prescribed. (par. 31)

12. Claim 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers, and in view of Clark et al. (US 6171112 B1)

[claim 6, 7] Myers discloses the method of claim 1 as explained in the rejection of claim 1. However, Myers does not expressly disclose a method further comprising the step of requesting confirmation of receipt of the correspondence and the step of archiving the correspondence with a notation as to whether or not the confirmation of receipt was received.

Clark discloses a method include the step of requesting confirmation of receipt of a correspondence from a patient user (i.e. prompting the user to sign whether of not they received information regarding their procedure) and the step of archiving the correspondence with a notation as to whether or not the confirmation of receipt was received. (e.g. signature sheet is printed out and stored with patient record) (col. 25, lines 28-57) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Myers with the teaching of Clark to request confirmation and record/archive whether the patient received a particular

document. As suggested by Clark, one would have been motivated to include this feature to establish an archivable record that the patient has been presented with particular information, which can be retrieved and observed for later use. (col. 3, lines 45-55)

[claim 8] Myers discloses a method as described in claim 6 , further comprising the step of providing an attachment with the correspondence, wherein the attachment is selected from the group consisting of: a laboratory requisition, prescription for ordering subsequent clinical tests, a prescription for a medication, a prescription for therapy, a portion of text describing information about subsequent clinical tests, test results, symptoms, health conditions, a prescribed medication, a prescribed therapy, a plurality of recommendations for lifestyle modification, screening, and interactions with health care providers, and a referral to a health care provider. (col. 8, lines 45-54-- "*Please read the attached documentation describing what cholesterol is, why it's important and how you can manage your own cholesterol;*" col.10, lines 1-25—provides information on interactions referral to physicians, recommendations on lifestyle)

13. Claims 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Filteau, in view of McCormick (US 2002/0035484).

[claim 24] Filteau discloses a method comprising the steps of:

- providing a display device and an interface for facilitating interaction between a human and a processor, providing a repository of snippets including patient text, providing a database including patient data; (Figure 1, 7A)
- viewing information regarding a patient including at least one test result using said display device; (Figure 8A)
- selecting at least one snippet from said repository of snippets; (Figure 7B, par. 82)
- interacting with said snippet using said interface to select at least a portion of said snippet; (par. 82-83)

Filteau discloses the method as described. Filteau further discloses generating a patient communication (par. 53-54; par 84-86; Figure 8A—patient communication because it has the information of a patient) but does not expressly disclose sending said patient communication including a prescription to said patient.

McCormick discloses a method including the step of automatically generating a prescription for a patient based upon the diagnostic results and automatically electronically sending a patient communication including said prescription to the patient. (pars 47, 54-55,58-59; par. 88 Figure 1B (step 230)—prescription electronically generated and transmitted to pharmacy, given to patient or sent to PBM to be mailed to patient home: *The patient may also be interested having the drugs (all or some) sent to his or her home by mail order.)* At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Filteau with the

teaching of McCormick to electronically send a prescription with diagnostic report to the patient. One would have been motivated to include this feature to provide better customer service and to establish a competitive advantage since not having the automated data entry would have a negative customer image, (par. 56).

[claim 25] Filteau and Crane describe the method of claim 24, as explained in the rejection of claim 24. Filteau does not disclose providing a prescription.

McCormick discloses a method wherein said generating the prescription for the patient includes providing a security feature designed to prevent duplication of said prescription. (par. 87-88—use of barcoding, electronic transmission of the prescription to minimize fraud) At the time of the applicant's invention, it would have been obvious to modify the method of Filteau with the teaching of McCormick. One would have been motivated to include this feature to further streamline the healthcare process and saving the patient time, while also preventing prescription abuse.

Response to Arguments

14. Applicant's arguments with respect to claims 1-16 and 24-25 have been considered but are moot in view of the new ground(s) of rejection.

In response the amendments, one or more new references has/have been applied.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- Walker et al. (US 7461079B2)
- De la Huerga (US 6272505B1)
- Dvorak et al. (US 6983423B2) .

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL L. PORTER whose telephone number is (571) 272-6775. The examiner can normally be reached on M-F, 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Morgan can be reached on (571) 272-6773. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/R. L. P./
Examiner, Art Unit 3626

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686